



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 10

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August 11, 2008

Reply To: OEA095

**MEMORANDUM**

SUBJECT: Review of the DRAFT *Risk Assessment Approach for Evaluating Potential Risks from Consuming Breast Milk* for the Portland Harbor Superfund Site

FROM: Dana Davoli  
Risk Assessor

TO: EPA Reviewers

The Portland Harbor Superfund Site is a 12 mile reach of the Willamette River in Portland, Oregon. A Remedial Investigation and Feasibility Study (RI/FS) was initiated by a group of potentially responsible parties known as the Lower Willamette Group (LWG) in 2001. The RI has resulted in the chemical analysis of sediment, surface water and fish tissue collected at the site. Fish tissue collected at the site are contaminated by polychlorinated biphenyls (PCBs), chlorinated dibenzo dioxins and furans (dioxin) and organochlorine pesticides such as DDT at concentrations that pose a risk to human health.

The governmental group that is reviewing the human health risk assessment (HHRA) and other risk related information for the Portland Harbor (PH) Superfund site (Mike Poulsen (Oregon DEQ), David Farrer (Oregon Office of Environmental Public Health) and myself, Dana Davoli (USEPA, Region 10)) has been concerned about the potential risks to infants from consuming chemicals in breast milk as a result of maternal exposure to eating contaminated fish from the PH site. EPA has directed the LWG to include the breast-milk scenario in the HHRA and has committed to providing the appropriate methodology for this scenario to the LWG. We prepared the attached memorandum, which presents a recommended approach for evaluating site risks from the breast-feeding exposure route, and would very much appreciate your review and comments on this memorandum.

The memorandum presents a draft methodology for assessing infant risk from consuming breast milk that relies heavily on EPA's *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*<sup>i</sup> (Combustion Guidance), *Exposure Factors Handbook*<sup>ii</sup>, *Child-Specific Exposure Factors Handbook*<sup>iii</sup>, and examples from other hazardous waste sites, such as the Housatonic river project in Massachusetts<sup>iv</sup>.

This memorandum includes exposure and risk equations for the breast milk scenario, as well as an example risk characterization assuming ingestion of fish contaminated with PCBs. Because the benefits to infants are so substantial from breast-feeding, we consider it appropriate to discuss the benefits issue in the risk assessment. We therefore will also be developing a Health Consultation from the Oregon Office of Environmental Public Health that presents the risks and benefits of consuming contaminated breast milk that will need to be included in the PH HHRA.

In reviewing the attached memorandum, we are especially interested in your comments on the following:

1. Should exposure to a nursing infant via breast milk be evaluated in the site-specific HHRA for the PH Superfund site? Is there sufficient confidence in the estimated cancer risks and non-cancer hazards calculated in this document such that they could be used to develop sediment remediation (clean-up) goals for the PH Superfund site?

Is there a reason why this scenario should not be included in all Superfund and RCRA site-specific risk assessments where mother's exposure to contaminants in sediment, soil, and other media could present a risk to breast-feeding infants?

2. In the memorandum, the recommended approach is to characterize the incremental cancer risks and non-hazard hazard quotients for a nursing infant exposed for one year (birth to 1 year of age). For estimating the PCB cancer risk, the IRIS slope factor was used. For estimating non-cancer Hazard Quotients (HQs), the ATSDR intermediate-duration PCB MRL was used<sup>v</sup>. ATSDR defines intermediate-duration exposure as two weeks to one year whereas EPA's chronic RfD was established for chronic exposures of 7 years to a lifetime. The ATSDR intermediate-duration MRL was assumed to be a more appropriate toxicity value than the IRIS RfD for PCBs.

Are both of these risk characterizations (cancer and non-cancer) valid and should both be used? Is use of the ATSDR intermediate-duration MRL appropriate for calculating the HQ? Are there uncertainties in either method that have not been discussed sufficiently? It should be noted that estimates of cancer risk and non-cancer hazards are included in EPA's *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*.

3. In the Uncertainty Section of the memorandum, other potential risk characterizations are discussed and compared to the recommended approach. These include: (a) Calculating a HQ for a one year exposure to breast-milk using the EPA RfD for PCBs rather the ATSDR MRL; and (b) Calculating exposure for a child assuming consumption of breast milk for 1 year and fish consumption for six years. These 7 year exposures were then used to calculate cancer risk and the HQ using the EPA RfD.

Do either of these approaches have more validity than the recommended approach?

4. In the Uncertainty Section, we also looked at the reduction in body burden of PCB during a year of breast feeding to see if that could result in reduced concentrations in breast milk. This assumed that there is no additional consumption of contaminated fish during this period.

Should this calculation be included in the recommended approach?

5. At other sites, including the Housatonic River site, EPA presented the potential risks from breast milk consumption as a ratio to background risk rather than as an excess lifetime cancer risk or hazard quotient.

Is there any reason why this approach is preferable to the recommended approach that characterizes cancer risk and an HQ? For the comparison of estimated breast milk concentrations from the PH site to general population concentrations, there is uncertainty and variability in of background concentrations. Are there other data on background concentrations that should be used instead of the ones on this document?

We very much appreciate any time that you can devote to this review. Please call me (206 553-2135) or e-mail me ([davoli.dana@epa.gov](mailto:davoli.dana@epa.gov)) if you have any questions. It would also be useful to know if you are willing and able to provide a review of this memorandum as soon as possible. EPA has committed to provide this methodology to the LWG and to resolve issues related to the method by early September. Therefore, we would very much appreciate your comments by Friday, August 29.

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<sup>i</sup> U. S. EPA. *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*. (EPA 530-R-05-006, September 2005).

<sup>ii</sup> U.S. EPA. *Exposure Factors Handbook*. National Center for Environmental Assessment, Office of Research and Development. August 1997.

<sup>iii</sup> U.S. EPA. *Child-Specific Exposure Factors Handbook*. National Center for Environmental Assessment, Office of Research and Development. EPA-600-P-00-002B, Interim Report. September 2002.

<sup>iv</sup> U.S. Army Corps of Engineers, U.S. EPA. *Human Health Risk Assessment, GE/Housatonic River Site, Rest of River*, Volume 1. February 2005

<sup>v</sup> Agency for Toxic Substances and Disease Registry (ATSDR). *Toxicological Profile for Polychlorinated Biphenyls* (Update, November 2000).